

General

Guideline Title

Management of suspected ovarian masses in premenopausal women.

Bibliographic Source(s)

Royal College of Obstetricians and Gynaecologists (RCOG), British Society of Gynaecological Endoscopy (BSGE). Management of suspected ovarian masses in premenopausal women. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2011 Nov. 14 p. (Green-top guideline; no. 62). [74 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

In addition to these evidence-based recommendations, the guideline developer also identifies points of best clinical practice in the original guideline document.

Classification of evidence levels (1++ to 4) and grades of recommendations (A-D) are defined at the end of the "Major Recommendations" field.

Preoperative Assessment of Women with Ovarian Masses

What Blood Tests Should Be Performed?

B - A serum CA-125 assay does not need to be undertaken in all premenopausal women when an ultrasonographic diagnosis of a simple ovarian cyst has been made (Kahraman et al., 2007; Zurawski et al., 1988; Van Calster et al., 2007).

C - Lactate dehydrogenase (LDH), alpha-fetoprotein (α -FP) and human chorionic gonadotrophin (hCG) should be measured in all women under age 40 with a complex ovarian mass because of the possibility of germ cell tumours.

What Imaging Should Be Employed in the Assessment of Suspected Ovarian Masses?

What Is the Role of Ultrasound in the Assessment of Suspected Ovarian Masses?

B - A pelvic ultrasound is the single most effective way of evaluating an ovarian mass with transvaginal ultrasonography being preferable due to its increased sensitivity over transabdominal ultrasound.

What Is the Role of the Routine Use of Computed Tomography and Magnetic Resonance Imaging (MRI) in the Assessment of Suspected Ovarian Masses?

C - At the present time the routine use of computed tomography and MRI for assessment of ovarian masses does not improve the sensitivity or specificity obtained by transvaginal ultrasonography in the detection of ovarian malignancy.

What Is the Best Way to Estimate the Risk of Malignancy?

B - An estimation of the risk of malignancy is essential in the assessment of an ovarian mass.

Which Risk of Malignancy Index (RMI) Should Be Used?

B - A systematic review of diagnostic studies concluded that the RMI I is the most effective for women with suspected ovarian cancer.

Refer to the original guideline document for a method for calculating the RMI I.

Is There Another Way to Estimate Accurately a Risk of Malignancy in Premenopausal Women without Using a CA-125?

B - There are simple ultrasound rules derived from the International Ovarian Tumor Analysis (IOTA) Group. The use of specific ultrasound morphological findings without CA-125 has been shown to have high sensitivity, specificity and likelihood ratios (Timmerman et al., 2008; Timmerman et al., 2010).

Please see Table 2 in the original guideline document for the IOTA Group ultrasound 'rules' to classify masses as benign (B-rules) or malignant (M-rules).

Management of Ovarian Masses Presumed to Be Benign in Non-Emergency Situations

Can Asymptomatic Women with Simple Ovarian Cysts Be Managed Expectantly?

C - Women with small (less than 50 mm diameter) simple ovarian cysts generally do not require follow-up as these cysts are very likely to be physiological and almost always resolve within 3 menstrual cycles.

C - Women with simple ovarian cysts of 50–70 mm in diameter should have yearly ultrasound follow-up and those with larger simple cysts should be considered for either further imaging (MRI) or surgical intervention.

How Should Persistent, Asymptomatic Ovarian Cysts Be Managed?

C - Ovarian cysts that persist or increase in size are unlikely to be functional and may warrant surgical management.

Does the Use of Combined Oral Contraceptives Help in the Treatment of Functional Ovarian Cysts?

A - The use of the combined oral contraceptive pill does not promote the resolution of functional ovarian cysts.

Is the Laparoscopic Approach Better for the Elective Surgical Management of Ovarian Masses?

A - The laparoscopic approach for elective surgical management of ovarian masses presumed to be benign is associated with lower postoperative morbidity and shorter recovery time and is preferred to laparotomy in suitable patients (Mais et al., 2003; Yuen et al., 1997; Panici et al., 2007; Fanfani et al., 2004).

A - Laparoscopic management is cost-effective because of the associated earlier discharge and return to work (Damiani et al., 1998).

C - In the presence of large masses with solid components (for example large dermoid cysts) laparotomy may be appropriate.

Should an Ovarian Cyst Be Aspirated?

B - Aspiration of ovarian cysts, either vaginally or laparoscopically, is less effective and is associated with a high rate of recurrence.

How Should an Ovarian Mass Be Removed?

A - Where possible removal of benign ovarian masses should be via the umbilical port. This results in less postoperative pain and a quicker retrieval time than when using lateral ports of the same size.

Definitions:

Grades of Recommendations

A - At least one meta-analysis, systematic review or randomised controlled trial rated as 1++, and directly applicable to the target population; *or*

A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results

B - A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C - A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D - Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Point - Recommended best practice based on the clinical experience of the guideline development group

Classification of Evidence Levels

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

1- Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

2++ High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal

2+ Well-conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal

2- Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal

3 Non-analytical studies, e.g., case reports, case series

4 Expert opinion

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Ovarian masses (cysts)

Guideline Category

Diagnosis

Evaluation

Management

Risk Assessment

Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Oncology

Radiology

Surgery

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To provide information, based on clinical evidence, to assist clinicians with the initial assessment and appropriate management of suspected ovarian masses in the premenopausal woman
- To clarify when ovarian masses can be managed within a 'benign' gynaecological service and when referral into a gynaecological oncological service should occur

Target Population

Premenopausal women with suspected ovarian mass (non-acute)

Note: The ongoing management of borderline ovarian tumours is outside the remit of this guideline. The laparoscopic management of highly suspicious or known ovarian malignancies is also outside the scope of this guideline. In addition, the guideline does not specifically address the acute presentation of ovarian cysts or the management of ovarian cysts in pregnant women.

Interventions and Practices Considered

Diagnosis/Evaluation/Risk Assessment

1. Blood tests: CA-125, lactate dehydrogenase (LDH), alpha-fetoprotein, and human chorionic gonadotrophin (hCG)
2. Pelvic ultrasound (transvaginal or transabdominal)
3. Computed tomography and magnetic resonance imaging (MRI) (not recommended routinely)
4. Estimating risk of malignancy of ovarian masses (use of Risk of Malignancy Index or the ultrasound 'rules' derived from the International Ovarian Tumor Analysis [IOTA] Group)

Management

1. Expectant management for simple small ovarian cysts
2. Yearly ultrasound follow-up
3. Further MRI or surgical intervention

4. Use of combined oral contraceptives (not recommended)
5. Laparoscopic surgical approach versus laparotomy
6. Laparoscopic or transvaginal aspiration of ovarian cysts in highly selected cases
7. Oophorectomy
8. Removal of benign ovarian masses via the umbilical port

Major Outcomes Considered

- Sensitivity and specificity of diagnostic tests and indices
- Rate of postoperative complications
- Recurrence rates
- Success of surgery

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

This guideline was developed using standard methodology for developing RCOG Green-top guidelines. The Cochrane Library (including the Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews and Effects [DARE] and EMBASE), Turning Research into Practice (TRIP), Medline and PubMed (electronic databases) were searched for relevant papers. The search was restricted to articles published between 1966 and May 2011 and performed by the British Society for Gynaecological Endoscopy (BSGE) using RCOG methodology. The databases were searched using the relevant medical subject heading terms including all subheadings and this was combined with a keyword search. The medical subject heading search included 'adnexa', 'ovary' and 'management'. The search was limited to humans and papers in the English language. Relevant guidelines were also searched using the same criteria in the National Guideline Clearinghouse, the National electronic Library for Health, the Organising Medical Networked Information (OMNI) and the Canadian Medical Association (CMA) Infobase.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Classification of Evidence Levels

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias

1– Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias

2++ High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal

2+ Well-conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal

2- Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal

3 Non-analytical studies, e.g., case reports, case series

4 Expert opinion

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Once the evidence has been collated for each clinical question it needs to be appraised and reviewed (refer to section 3 in "Development of RCOG Green-top guidelines: producing a clinical practice guideline" for information on the formulation of the clinical questions; see the "Availability of Companion Documents" field). For each question, the study type with least chance of bias should be used. If available, randomised controlled trials (RCTs) of suitable size and quality should be used in preference to observational data. This may vary depending on the outcome being examined.

The level of evidence and the grade of the recommendations used in this guideline originate from the guidance by the Scottish Intercollegiate Guidelines Network (SIGN) Grading Review Group, which incorporates formal assessment of the methodological quality, quantity, consistency, and applicability of the evidence base. The methods used to appraise individual study types are available from the SIGN Web site (www.sign.ac.uk/methodology/checklists.html). An objective appraisal of study quality is essential, but paired reviewing by guideline leads may be impractical because of resource constraints.

Once evidence has been collated and appraised, it can be graded. A judgement on the quality of the evidence will be necessary using the grading system (see the "Rating Scheme for the Strength of the Evidence" field). Where evidence is felt to warrant 'down-grading', for whatever reason, the rationale must be stated. Evidence judged to be of poor quality can be excluded. Any study with a high chance of bias (either 1- or 2-) will be excluded from the guideline and recommendations will not be based on this evidence. This prevents recommendations being based on poor-quality RCTs when higher-quality observational evidence is available.

Methods Used to Formulate the Recommendations

Expert Consensus

Informal Consensus

Description of Methods Used to Formulate the Recommendations

Guideline Development

The development of guidelines involves more than the collation and reviewing of evidence. Even with high-quality data from systematic reviews of randomised controlled trials, a value judgement is needed when comparing one therapy with another. This will therefore introduce the need for consensus.

Royal College of Obstetricians and Gynaecologists (RCOG) Green-top guidelines are drafted by nominated developers, in contrast to other guideline groups such as the National Institute for Health and Clinical Excellence (NICE) and the Scottish Intercollegiate Guidelines Network (SIGN), who use larger guideline development groups. Equally, in contrast to other guideline groups, the topics chosen for development as Green-top guidelines are concise enough to allow development by a smaller group of individuals.

In agreeing the precise wording of evidence-based guideline recommendations and in developing consensus-based 'good practice points', the

Guidelines Committee (GC) will employ an informal consensus approach through group discussion. In line with current methodologies, the entire development process will follow strict guidance and be both transparent and robust. The RCOG acknowledges that formal consensus methods have been described, but these require further evaluation in the context of clinical guideline development. It is envisaged that this will not detract from the rigor of the process but prevent undue delays in development.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendations

A - At least one meta-analysis, systematic review or randomised controlled trial rated as 1++, and directly applicable to the target population; *or*

A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results

B - A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C - A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D - Evidence level 3 or 4; *or*

Extrapolated evidence from studies rated as 2+

Good Practice Point - Recommended best practice based on the clinical experience of the guideline development group

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Following discussion in the Guidelines Committee (GC), each Green-top guideline is formally peer reviewed. At the same time, the draft guideline is published on the Royal College of Obstetricians and Gynaecologists (RCOG) Web site for further peer discussion before final publication.

All comments will be collated by the RCOG and tabulated for consideration by the guideline leads. Each comment will require discussion. Where comments are rejected then justification will need to be made. Following this review, the document will be updated and the GC will then review the revised draft and the table of comments.

Once the GC signs-off on the guideline, it is submitted to the Standards Board for approval before final publication.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Damiani G, Campo S2, Dargenio R, Garcea N. Laparoscopic vs. laparotomic ovarian cystectomy in reproductive age women: an economic evaluation. *Gynaecol Endosc.* 1998;7:19-23.

Fanfani F, Fagotti A, Ercoli A, Bifulco G, Longo R, Mancuso S, Scambia G. A prospective randomized study of laparoscopy and minilaparotomy in the management of benign adnexal masses. *Hum Reprod.* 2004 Oct;19(10):2367-71. [PubMed](#)

Kahraman K, Ozguven I, Gungor M, Atabekoglu CS. Extremely elevated serum CA-125 level as a result of unruptured unilateral endometrioma: the highest value reported. *Fertil Steril.* 2007 Oct;88(4):968.e15-7. [PubMed](#)

Mais V, Ajossa S, Mallarini G, Guerriero S, Oggiano MP, Melis GB. No recurrence of mature ovarian teratomas after laparoscopic cystectomy. *BJOG.* 2003 Jun;110(6):624-6. [PubMed](#)

Panici PB, Muzii L, Palaia I, Mancini N, Bellati F, Plotti F, Zullo M, Angioli R. Minilaparotomy versus laparoscopy in the treatment of benign adnexal cysts: a randomized clinical study. *Eur J Obstet Gynecol Reprod Biol.* 2007 Aug;133(2):218-22. [PubMed](#)

Timmerman D, Ameye L, Fischerova D, Epstein E, Melis GB, Guerriero S, Van Holsbeke C, Savelli L, Fruscio R, Lissoni AA, Testa AC, Veldman J, Vergote I, Van Huffel S, Bourne T, Valentin L. Simple ultrasound rules to distinguish between benign and malignant adnexal masses before surgery: prospective validation by IOTA group. *BMJ.* 2010;341:c6839. [PubMed](#)

Timmerman D, Testa AC, Bourne T, Ameye L, Jurkovic D, Van Holsbeke C, Paladini D, Van Calster B, Vergote I, Van Huffel S, Valentin L. Simple ultrasound-based rules for the diagnosis of ovarian cancer. *Ultrasound Obstet Gynecol.* 2008 Jun;31(6):681-90. [PubMed](#)

Van Calster B, Timmerman D, Bourne T, Testa AC, Van Holsbeke C, Domali E, Jurkovic D, Neven P, Van Huffel S, Valentin L. Discrimination between benign and malignant adnexal masses by specialist ultrasound examination versus serum CA-125. *J Natl Cancer Inst.* 2007 Nov 21;99(22):1706-14. [PubMed](#)

Yuen PM, Yu KM, Yip SK, Lau WC, Rogers MS, Chang A. A randomized prospective study of laparoscopy and laparotomy in the management of benign ovarian masses. *Am J Obstet Gynecol.* 1997 Jul;177(1):109-14. [PubMed](#)

Zurawski VR Jr, Orjaseter H, Andersen A, Jellum E. Elevated serum CA 125 levels prior to diagnosis of ovarian neoplasia: relevance for early detection of ovarian cancer. *Int J Cancer.* 1988 Nov 15;42(5):677-80. [PubMed](#)

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- More accurate identification of benign vs malignant ovarian mass in the premenopausal women
- Appropriate referral to gynaecological oncology units
- Appropriate management of ovarian masses
- Appropriate use of laparoscopic techniques

Potential Harms

Surgical complications

Contraindications

Contraindications

On rare occasions, the laparoscopic approach may be specifically contraindicated in an individual patient.

Qualifying Statements

Qualifying Statements

- These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.
- The Royal College of Obstetricians and Gynaecologists (RCOG) produces guidelines as an educational aid to good clinical practice. They present recognised methods and techniques of clinical practice, based on published evidence, for consideration by obstetricians and gynaecologists and other relevant health professionals. The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor or other attendant in the light of clinical data presented by the patient and the diagnostic and treatment options available within the appropriate health services. This means that RCOG guidelines are unlike protocols or guidelines issued by employers, not being intended to be prescriptive directions defining a single course of management. Departure from the local prescriptive protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Royal College of Obstetricians and Gynaecologists (RCOG), British Society of Gynaecological Endoscopy (BSGE). Management of suspected ovarian masses in premenopausal women. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2011 Nov. 14 p. (Green-top guideline; no. 62). [74 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Nov

Guideline Developer(s)

British Society for Gynecological Endoscopy - Medical Specialty Society

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

Source(s) of Funding

Royal College of Obstetricians and Gynaecologists

Guideline Committee

Guidelines Committee

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Guideline Committee Lead Reviewers: Dr AJ Thomson MRCOG, Paisley, Scotland; Dr RG Ashe FRCOG, County Antrim, Northern Ireland

Financial Disclosures/Conflicts of Interest

Conflicts of interest: none declared.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the [Royal College of Obstetricians and Gynaecologists \(RCOG\) Web site](#) .

Availability of Companion Documents

The following are available:

- Development of RCOG Green-top guidelines: policies and processes. Clinical Governance Advice No 1a. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 6 p. Electronic copies: Available from the [Royal College of Obstetricians and Gynaecologists \(RCOG\) Web site](#) .
- Development of RCOG Green-top guidelines: producing a scope. Clinical Governance Advice No 1b. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 4 p. Electronic copies: Available from the [RCOG Web site](#) .
- Development of RCOG Green-top guidelines: producing a clinical practice guideline. Clinical Governance Advice No 1c. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 13 p. Electronic copies: Available from the [RCOG Web site](#) .
- Development of RCOG Green-top guidelines: consensus methods for adaptation of Green-top guidelines. Clinical Governance Advice No 1d. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2010 Feb. 9 p. Electronic copies: Available from the [RCOG Web site](#) .

In addition, suggested audit topics can be found in section 7 of the [original guideline document](#) .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on May 14, 2012. This summary was verified by the guideline developer on June 18, 2012.

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